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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,683	04/21/2000	Lawrence Xavier Webb, M.D.	F. 003	6497

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,683

Applicant(s)

WEBB, M.D., LAWRENCE XAVIER

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,11,12,15-18,20-25, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 26 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-29 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,11,12,15-18,20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 26 and 27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Response to Arguments

1. Applicant's arguments filed on 4/23/02 have been fully considered but they are not persuasive. Also, claims 26 and 27 are withdrawn from consideration as being directed to a non-elected invention.

Regarding Claims 1-10

With respect to the orthogonal, and rectilinear coordinates not being taught by Mosby'985, the Examiner respectfully disagrees. Mosby'985 teaches use of orthogonal, and rectilinear coordinates as clearly indicated in Figures 1 and as explained in column 5, lines 45-47, wherein it is explained that the conforming grid used, has vertical and horizontal lines. Mosby'985 also uses polar coordinates on the same grid, in addition to the vertical and horizontal lines (orthogonal, and rectilinear coordinates).

With respect to the "box-liked" apparatus, Applicant's claim language does not exclude such an apparatus or its use, so arguments with respect to features that are not excluded with the current claim language are inadequate.

The argument regarding the intended surface of use by Mosby'985 is also misplaced for the reason that the current claim language of the instant invention does not exclude such a use. In addition, even assuming *arguendo* that it did, such language would not render the current invention patentable because it is well within the knowledge of skilled artisans to conform or adjust use of the apparatus for the selected area of interest.

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Regarding Claims 11-12

With respect to claims 11-12, the arguments presented have been fully considered but they are not persuasive. Mosby'985 refers to the grid he is using as "conforming", he refers to it as "a conforming, flat, pliable sheet with a grid display" (col. 2, lines 45-48). The definition of "conforming" inherently includes "shaping" or an alternative phraseology as disclosed by the current application as "shrink-fitted." Therefore arguments with respect to the shrink fitting are not persuasive, as Mosby'985 uses the word "conforming" to describe the pliable sheet.

Regarding Claims 16-18, 20 and 21

With respect to claims 16-18, 20 and 21, the arguments presented have been fully considered but they are not persuasive. The use of the term "conical" or even the "cut-out" does not define over Mosby'985. Mosby'985, thought-out his figures, for example look at Figure 3 (also see col. 5, lines 54-58), describes a "cut-out" for the nipple, and as evident by the shape of the breast, conical would be one of many geometrical ways for describing the human breast. In addition it is inherent that the invention of Mosby'985 is applicable to any size of breast. Therefore, these arguments are not persuasive.

Regarding Claims 22-27

With respect to claims 22-25, the use of the "unobstructed access" so as to allow the operator hand to "adjacent" the indicia does not define over Mosby'985. Mosby'985 teaches the use of its apparatus for biopsy, inherently the operator's hand will be proximately to the target in order to accurately aim the needle, this inherently includes that the hand will be adjacent the indicia. Again, the reference to the "box-like" apparatus is inapplicable because the current invention by its claimed language does not exclude such use.

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Claim 26, constitutes a claim under election by original presentation, as implantation is an area that was not previously searched and places an unreasonable burden on the examiner to search a substantial search area.

Claim 27, constitutes a claim under election by original presentation, as the "orienting a beam of light" is an area that was not previously searched and places an unreasonable burden on the examiner to search a substantial search area.

Regarding Claims 28-29

Claims 28 and 29 are allowable.

For the above reasons, this rejection is maintained and made Final.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosby'985 in view of 3MiobanDrapes (1987) both of record.

Mosby'985 teaches all the features of the instant invention including a conforming grid made of pliable compliant plastic sheet like material allowing for marking with radiopaque and visible lines, letters and numbers, conforming to the outline of the subject matter and becoming its own standard reference used in biopsy or **biopsy surgery** permitting the entrance of a biopsy needle (see col. 6, lines 38-47, col. 7, lines 1-10 and all claims referring to biopsy surgery and perforation of the plastic with stylet and biopsy needles). Since Mosby'985 is teaching use of

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the plastic grid during surgery it is inherent that precautions are taken to avoid infection, however, Mosby'985 does not in particular teach the use of plastic made of iodophor as drapes. 3MiobanDrapes (1987) teach the use of plastic iodophor adhesive drapes providing for sterile conditions. It would have been obvious to one skilled in the art at the time that the invention was made to have utilized the sterile iodophor drapes in the invention of Mosby'985 as the pliable compliant plastic sheet like material allowing for marking with radiopaque and visible lines, letters and numbers, conforming to the outline of the subject matter, in order to provide for sterile conditions and fight skin bacteria during the surgery as taught in 3MiobanDrapes (1987, page 3/4).

Furthermore, Mosby'985 teaches a localization procedure and device which provides for complete utilization of a maximum of two planes of evaluation (col. 3, lines 58-62).

Election/Restrictions

Newly submitted claims 26-27 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 26, introduces implantation which is an area that was not previously searched and places an unreasonable burden on the examiner to search a substantial search area. Claim 27, constitutes a claim under election by original presentation, as the "orienting a beam of light" is an area that was not previously searched and places an unreasonable burden on the examiner to search a substantial search area.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26 and 27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Allowable Subject Matter

3. Claims 28-29 are allowed.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Muller'762 teaches a multi-purpose integrated surgical drape.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Wed. - Wed., 7:00 a.m.-5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 703 308-7635. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-0758 for regular communications and 703 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700



EMM

July 12, 2002